

as well as the thermal interaction effects of the waste packages, backfill, drip shields, rock, and unsaturated zone and saturated zone water, must be conducted.

(b) The testing must be initiated as early as practicable.

(c) If backfill is included in the repository design, a test must be conducted to evaluate the effectiveness of backfill placement and compaction procedures against design requirements before permanent backfill placement is begun.

(d) Tests must be conducted to evaluate the effectiveness of borehole, shaft, and ramp seals before full-scale operation proceeds to seal boreholes, shafts, and ramps.

§ 63.134 Monitoring and testing waste packages.

(a) A program must be established at the geologic repository operations area for monitoring the condition of the waste packages. Waste packages chosen for the program must be representative of those to be emplaced in the underground facility.

(b) Consistent with safe operation at the geologic repository operations area, the environment of the waste packages selected for the waste package monitoring program must be representative of the environment in which the wastes are to be emplaced.

(c) The waste package monitoring program must include laboratory experiments that focus on the internal condition of the waste packages. To the extent practical, the environment experienced by the emplaced waste packages within the underground facility during the waste package monitoring program must be duplicated in the laboratory experiments.

(d) The waste package monitoring program must continue as long as practical up to the time of permanent closure.

Subpart G—Quality Assurance

§ 63.141 Scope.

As used in this part, *quality assurance* comprises all those planned and systematic actions necessary to provide adequate confidence that the geologic repository and its structures, systems, or components will perform satisfac-

torily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system that provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

§ 63.142 Quality assurance criteria.

(a) *Introduction and Applicability.* DOE is required by § 63.21(c)(20) to include in its safety analysis report a description of the quality assurance program to be applied to all structures, systems, and components important to safety, to design and characterization of barriers important to waste isolation, and to related activities. These activities include: site characterization; acquisition, control, and analyses of samples and data; tests and experiments; scientific studies; facility and equipment design and construction; facility operation; performance confirmation; permanent closure; and decontamination and dismantling of surface facilities. The description must indicate how the applicable quality assurance requirements will be satisfied. DOE shall include information pertaining to the managerial and administrative controls to be used to ensure safe operation in its safety analysis report. High-level waste repositories include structures, systems, and components that prevent or mitigate the consequences of postulated event sequences or that are important to waste isolation capabilities that could cause undue risk to the health and safety of the public. The pertinent requirements of this subpart apply to all activities that are important to waste isolation and important to safety functions of those structures, systems, and components. These activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, modifying, site characterization, performance confirmation, permanent closure, decontamination, and dismantling of surface facilities.

(b) *Organization.* DOE shall establish and execute a quality assurance program. DOE may delegate to others,

such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of it, but DOE retains responsibility for it.

(1) The authority and duties of persons and organizations performing activities affecting the functions of structures, systems, and components that are important to waste isolation and important to safety must be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of:

(i) Assuring that an appropriate quality assurance program is established and effectively executed; and

(ii) Verifying that activities important to waste isolation and important to safety functions have been correctly performed by checking, auditing, and inspection of structures, systems, and components.

(2) The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. The persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided.

(3) Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may take various forms provided that the persons and organizations assigned the quality assurance functions have this required authority and organizational freedom. Irrespective of the organizational structure, the individual(s) assigned the responsibility for assuring effective execution of any portion of the quality assurance program at any location where activities subject to 10 CFR part 63 are being performed must have direct access to the levels of man-

agement as may be necessary to perform this function.

(c) *Quality assurance program.* DOE shall establish a quality assurance program that complies with the requirements of this subpart at the earliest practicable time, consistent with the schedule for accomplishing the activities. This program must be documented by written policies, procedures, or instructions and must be carried out throughout facility life in accordance with those policies, procedures, or instructions.

(1) DOE shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program must control activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety.

(2) Activities affecting quality must be accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied.

(3) The program must take into account the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test. The program must provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

(4) DOE shall regularly review the status and adequacy of the quality assurance program. Management of other organizations participating in the quality assurance program shall regularly review the status and adequacy of that part of the quality assurance program which they are executing.

(d) *Design control.* (1) DOE shall establish measures to assure that applicable regulatory requirements and the design basis, as defined in § 63.2 and as specified in the license application, for

those structures, systems, and components to which this subpart applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must assure that appropriate quality standards are specified and included in design documents and that deviations from such standards are controlled. Measures must also be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are important to waste isolation and important to safety functions of the structures, systems and components.

(2) DOE shall establish measures to identify and control design interfaces and for coordination among participating design organizations. These measures must include the establishment of procedures among participating design organizations for the review, approval, release, distribution, and revision of documents involving design interfaces.

(i) The design control measures must provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program. The verifying or checking process must be performed by individuals or groups other than those who performed the original design. These individuals may be from the same organization. If a test program is used to verify the adequacy of a specific design feature in lieu of other verifying or checking processes, it must include suitable qualifications testing of a prototype unit under the most adverse design conditions. Design control measures must be applied to items such as: criticality physics, stress, thermal, hydraulic, and preclosure and postclosure analyses; compatibility of materials; accessibility for inservice inspection, maintenance and repair; and delineation of acceptance criteria for inspections and tests.

(ii) Design changes, including field changes, must be subject to design control measures commensurate with those applied to the original design and be approved by the organization that performed the original design unless

the applicant designates another responsible organization.

(e) *Procurement document control.* DOE shall establish measures to assure that applicable regulatory requirements, design bases, and other requirements necessary to assure adequate quality are suitably included or referenced in the documents for procurement of material, equipment, and services, whether purchased by the licensee or applicant or by its contractors or subcontractors. To the extent necessary, procurement documents must require contractors or subcontractors to provide a quality assurance program consistent with the pertinent provisions of this section.

(f) *Instructions, procedures, and drawings.* Activities affecting quality must be prescribed by documented instructions, procedures, or drawings of a type appropriate to the circumstances and must be accomplished in accordance with these instructions, procedures, or drawings. Instructions, procedures, or drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

(g) *Document control.* DOE shall establish measures to control the issuance of documents, such as instructions, procedures, and drawings, including changes to them that prescribe all activities affecting quality. These measures must assure that documents, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to documents must be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

(h) *Control of purchased material, equipment, and services.* DOE shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

(1) These measures must include appropriate provisions for source evaluation and selection, objective evidence

of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products upon delivery.

(2) Documentary evidence that material and equipment conform to the procurement requirements must be available at the high-level waste repository site before the material and equipment are installed or used. This documentary evidence must be retained at the high-level waste repository site and be sufficient to identify the specific requirements, such as codes, standards, or specifications, met by the purchased material and equipment.

(3) The effectiveness of the control of quality by contractors and subcontractors must be assessed by the licensee or applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services.

(i) *Identification and control of materials, parts, and components.* Measures must be established for the identification and control of materials, parts, and components, including partially fabricated assemblies. These measures must assure that identification of the item is maintained by heat number, part number, serial number, or other appropriate means, either on the item or on records traceable to the item, as required throughout fabrication, erection, installation, and use of the item. These identification and control measures must be designed to prevent the use of incorrect or defective material, parts, and components.

(j) *Control of special processes.* DOE shall establish measures to assure that special processes, including welding, heat treating, and nondestructive testing, are controlled and accomplished by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

(k) *Inspection.* DOE shall establish and execute a program for inspection of activities affecting quality to verify conformance with the documented instructions, procedures, and drawings for accomplishing the activity. The inspection must be performed by individ-

uals other than those who performed the activity being inspected.

(1) Examinations, measurements, or tests of material or products processed must be performed for each work operation where necessary to assure quality. If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processing methods, equipment, and personnel must be provided. Both inspection and process monitoring must be provided when control is inadequate without both.

(2) If mandatory inspection hold points that require witnessing or inspecting by the applicant's designated representative and beyond which work may not proceed without the consent of its designated representative are required, the specific hold points must be indicated in appropriate documents.

(l) *Test control.* DOE shall establish a test program to assure that all testing required to demonstrate that structures, systems, and components important to safety will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate the requirements and acceptance limits contained in applicable design documents.

(1) The test program must include, as appropriate, proof tests prior to installation, preoperational tests, and operational tests during repository operation, of structures, systems, and components.

(2) Test procedures must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

(3) Test results must be documented and evaluated to assure that test requirements have been satisfied.

(m) *Control of measuring and test equipment.* DOE shall establish measures to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits.

(n) *Handling, storage, and shipping.* DOE shall establish measures to control the handling, storage, shipping, cleaning and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, specific moisture content levels, and temperature levels, must be specified and provided.

(o) *Inspection, test, and operating status.* DOE shall establish measures to indicate the status of inspections and tests performed on individual items of the high-level waste repository by markings such as stamps, tags, labels, routing cards, or other suitable means. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. Measures must also be established for indicating the operating status of structures, systems, and components of the high-level waste repository, such as by tagging valves and switches, to prevent inadvertent operation.

(p) *Nonconforming materials, parts, or components.* DOE shall establish measures to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures.

(q) *Corrective action.* DOE shall establish measures to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. If significant conditions are adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective ac-

tion taken must be documented and reported to appropriate levels of management.

(r) *Quality assurance records.* DOE shall maintain sufficient records to furnish evidence of activities affecting quality.

(1) The records must include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses.

(2) The records must also include closely-related data such as qualifications of personnel, procedures, and equipment.

(3) Inspection and test records must, at a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted.

(4) Records must be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.

(s) *Audits.* DOE shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audit results must be documented and reviewed by management having responsibility in the area audited. Followup action, including reaudit of deficient areas, must be taken where indicated.

§ 63.143 Implementation.

DOE shall implement a quality assurance program based on the criteria required by § 63.142.

§ 63.144 Quality assurance program change.

Changes to DOE's NRC-approved Safety Analysis Report quality assurance program description are processed as follows: